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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,838	06/30/2003	Alan Schaer	021574-000220US	5147

20350 7590 05/03/2006

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EXAMINER	
HORWAT, JENNIFER A	

ART UNIT	PAPER NUMBER
3768	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/611,838	SCHAER, ALAN	
	Examiner	Art Unit	
	Jennifer Horwat	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/10/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 49 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 49 and 50 recite the limitations "the balloons" and "the acoustically transmissive medium". There is insufficient antecedent basis for these limitations in the claims.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-9, 12-15, 20-23, 37, 38, 40-47, 50, 51, 54-56, 60 and 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Shadduck (US 6740082).

Shadduck discloses an instrument and method for treatment of the lower esophageal sphincter. Although much of the disclosure is directed to Rf sources,

Shadduck states that other sources of energy such as ultrasound or high-energy focused ultrasound known in the art my be used in place of the Rf source (col 8, lines 10-15). Energy is delivered to a targeted tissue volume to accomplish controlled remodeling of the tissue (col 2, lines 50-52), where the target tissue is an anatomic lumen, such as the esophagus or the urethra (col 2, line 60). The energy electively injures cells to induce a biological response, which causes collagen formation (col 3, line 5) and additionally causes ionic agitation (col 3, line 45), and shrinking of tissue (col 3, line 32) including contracting longitudinally (col 4, line 38), which reduces compliance of the tissue. The injury of cells inherently interrupts their normal functions, such as interrupting nerve pathways and the ability to absorb food. Intestinal metaplasia is just one type of tissue found in the esophagus, which may be selectively remodeled by the system and is merely an intended use of the system, which is inherently capable of destroying specific tissues in the esophagus. Alternative uses disclosed include endoscopically accessing a hiatal hernia in the abdominal cavity (col 17, lines 5-6) where the lumen would be the diaphragmatic sphincter.

Energy is used to heat temperature in the range of 40 to 70 degrees Celsius, which is within the range of 55 to 95 degrees (col 3, line 27). A sensor array is used to measure temperature levels of a portion of the wall in contact with the sensor (col 10, line 16-18), wherein the wall consists of more than just the luminal surface. Additionally, temperature measurements of surface temperatures along the lumen surface (col 10, line 50), which can also be used to ensure over a certain maximum temperature is not reached during treatment (col 11, line 18). A cooling means may be circulated to

maintain surface of the esophageal lumen (col 17, line 59). An elongate member, or catheter, with a working end is used to introduce the system to the lumen or target tissue (col 7, line 53-55). A balloon made of an elastomeric material is used which is inflatable until it contacts the surface of the target tissue in the wall of the LES (col 12, line 35-38). Alternatively, tissue may be captured between movable opposed elements (figure 12A, elements 252a and 252b) with transducers (figure 12A, elements 245a and 245b) that direct energy to the captured tissue. The instrument includes a working channel that allows an endoscope or another instrument to be introduced (col 6, lines 44-45).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Hutchinson, et al (US 6929608). Shadduck, as discussed above, substantially discloses the invention, as claimed, however fails to explicitly disclose the energy range used. Hutchinson teaches that it is well known in the art to use a range from 0 to 30 W/cm^2 (figure 11) for the deposition in body tissue for thermal therapy (col 1). It would have been obvious to one of ordinary skill in the art at the time of the

invention to modify the disclosure of Shadduck in light of the teachings in the reference by Hutchinson in order to use a well-known energy range for proper tissue treatment.

8. Claims 11, 24, 25, and 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Ingle, et al (US 6976492). Shadduck, as discussed above, substantially discloses the invention as claimed, however fails to explicitly disclose the duty cycle used and the use of a phased array. Ingle teaches the use of a 50% duty cycle (col 7, lines 26-29), which falls in the range of 10% to 100%, for the improved shrinking of tissues. Additionally, a phased array ultrasound transmitter is used (col 8, lines 50-51). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in light of the teachings in the reference by Ingle to include a 50% duty cycle for improved treatment of target tissues and a phased array for enhanced targeting flexibility (col 8, line 50).

9. Claims 17, 48, and 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Houser (US 5865801). Shadduck, as discussed above, substantially discloses the invention as claimed, however fails to disclose the use of axially spaced apart balloons. Houser discloses a system including balloons surrounding an ultrasonic transducer. The pair of balloons are axially spaced apart (figure 3) and thereby center the transducer. The balloon compartments are each filled with fluid and Houser further states that the balloon may be constructed to have any desired number of compartments. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in light of the

teachings in the reference by Houser to include multiple axially spaced balloons to advantageously provide better support and positioning capabilities.

10. Claims 16, 18, 19, 26, 27, 28, 30-34, 36, 52, 57, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Chapelon, et al (US 5720287). Shadduck, as discussed above, substantially discloses the invention as claimed, however fails to disclose details of the relationship between the balloon and the transducer itself. In regards to claims 19 and 27, Shadduck, as previously discussed, discloses cooling of the fluid medium in the balloon to cool the luminal surface as well as viewing the target tissue through an endoscope. In regards to claims 30-32, Shadduck additionally discloses a balloon that is expanded against the body lumen for treatment, including the area adjacent to the opening as well as the entire opening (figures 7a and 7b). Chapelon discloses a therapy probe for ultrasound therapy and further teaches a transducer probe surrounded by a flexible membrane (figure 9, element 120), which is filled with an acoustic-coupling liquid such as water or an oil (col 4, lines 41-44). The transducer is movable with respect to the flexible outer casing of the probe (col 2, line 15-16), which may be focused through pivotal mounting. The probe may be rotated, pivoted, or translated (col 8, lines 14-16) and multiple transducers may be used, exemplarily using one for imaging and one for treatment, as seen in figure 9. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shaddock in light of the teachings in the reference by Chapelon to include increased mobility of the probe and transducer to

advantageously increase the number of target areas able to be reached by the ultrasonic treatment.

11. Claim 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Chapelon as applied to claim 26 above, and further in view of Makower, et al (US 6302875). Shadduck in view of Chapelon, as discussed above, substantially discloses the invention as claimed, however fails to disclose the used of a circumferential array transducer. Makower discloses a system for an ultrasound catheter that may be inserted into blood vessels or other body lumens and further teaches the use of a circumferential array (claim 22). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in view of Chapelon in light of the teachings in the reference by Makower to include a circumferential array, as a luminal anatomical structure (col 1, line 28) is circumferential and therefore the use of this array will advantageously increase the number of target areas.

12. Claim 35 rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Chapelon as applied to claim 26 above, and further in view of Jang (US 4744366). Shadduck in view of Chapelon, as discussed above, substantially discloses the invention, as claimed, however fails to disclose the used of multiple coaxial balloons. Jang discloses a catheter, which analogously uses balloons to obtain proper placement of the catheter and to provide contact with a lumen wall. Additionally Jang teaches the use of multiple balloons that are independently inflated, and thereby translated, to provide desired positioning (figure 8). It would have been obvious to one

of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in view of Chapelon to include multiple coaxial balloons to provide improved control in positioning the catheter and a greater range of available balloon diameters.

13. Claims 39 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Sliwa, Jr., et al (US 2005/0245918). Shadduck, as discussed above, substantially discloses the invention as claimed, including capturing luminal tissue between opposed elements. However, Shadduck fails to disclose the use of a vacuum to draw tissue between said elements. Sliwa discloses a system for ablation of tissue in which the device, as in Shadduck, also comes into contact with the targeted tissue. Sliwa additionally teaches that a vacuum source (col 26, line 22) is used to hold the target tissue against the ablation device. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in light of the teachings in the reference by Sliwa to include a vacuum, as holding the target tissue improves the accuracy in treating only the desired tissue.

14. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck in view of Makower. Shadduck, as discussed above, substantially discloses the invention as claimed, however fails to disclose the used of a circumferential array transducer. Makower discloses a system for an ultrasound catheter that may be inserted into blood vessels or other body lumens and further teaches the use of a circumferential array (claim 22). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the disclosure of Shadduck in light of the teachings in the reference by Makower to include a circumferential array, as a luminal

anatomical structure (col 1, line 28) is circumferential and therefore the use of this array will advantageously increase the number of target areas.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Horwat whose telephone number is (571) 272-2811. The examiner can normally be reached on M-Th 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ELENI MANTIS-MERCADER
PRIMARY EXAMINER

jah
4/26/06